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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,738	07/20/2001	Jonathan Gressel	01/22289	8901

7590

08/27/2003

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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 08/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/889,738

Applicant(s)

GRESSEL ET AL.

Examiner

Russell Kallis

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-19, 22-29, 32-39, 42-61 and 84-91 is/are pending in the application.

4a) Of the above claim(s) 48-61 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-7, 12-18, 22-28, 32-38, 42-47 and 84-91 is/are rejected.

- 7) ☒ Claim(s) 8, 11, 19, 29 and 39 is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Claims 9-10, 20-21, 30-31, 40-41 and 62-83 are cancelled. Claims 1-8, 11-19, 22-29, 32-39, 42-61 and 84-91 are pending. Claims 48-61 are withdrawn. Claims 1-8, 11-19, 22-29, 32-39, 42-47 and 84-91 are examined.

Rejection of Claims 31, 41, 69, and 79 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments.

Rejection of Claims 14-18, 20-21, 24-28, 30-31, 62-69, and 72-79 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments.

#### *Claim Rejections - 35 USC § 112*

Claims 1-7, 12-18, 22-28, 32-38 and 42-47 remain and new Claims 84-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant asserts isolation of flavone-7-O-glucoside-2''-O-rhamnosyl-transferase from Pummelo, unattainable by traditional screening of cDNA libraries using oligonucleotide probes or antibodies, was successfully isolated using PCR with degenerate primers designed from fragments of the digested enzyme, and since the flavone-7-O-glucoside-2''-O-rhamnosyl-transferase activity encoded by the polynucleotides of the present invention is the only known example taught in the art, one of ordinary skill in the art would have a high expectation of isolating all polynucleotides having high homology (at least 80% sequence identity) to SEQ ID NO: 20 and that encode a flavone-7-O-glucoside-2''-O-rhamnosyl-transferase homologue from a

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plant species other than pommelo (response pages 10-11). Applicant further urges that the amendments to the claims to remove limitations directed towards fragment and sequence identities between 50% to 80%, or functional or active parts, and the claims are now only directed to sequences with high homology to SEQ ID NO: 20 (response page 12). Applicant has not described any other sequences that would encode a polypeptide having flavone-7-O-glucoside-2''-O-rhamnosyl-transferase activity, which residues when altered would not yield a functional enzyme or would retain the activity of the polypeptide, or which sequences of the peptide are conserved or are known motifs and would allow for isolation of functional equivalents. Thus Applicant has not described the genus comprising functional embodiments that fall within the range of 80% sequence identity to SEQ ID NO: 20 and 75% sequence identity to SEQ IDNO: 21.

Claims 1-7, 12-18, 22-28, 32-38 and 42-47 and new Claims 84-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant asserts that the antisense and sense methods of manipulating gene expression are well known in the art and recites examples where antisense oligos have been successfully used in treating several ailments known in humans (response page 14). Applicant should recognize it is well known in the art that treating any human ailment using antisense is highly unpredictable. For example, it is well known in the art of antisense methods in humans, that Tumor Necrosis Factor alpha and beta are made by the human immune system in response to the antisense molecule because the antisense RNA is seen as an antigen and thus eliminated from the

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system. Further, antisense treatments for ailments using polynucleotides that have 80% sequence identity are unpredictable as well as those methods directed towards using antisense for modifying gene expression in a plant simply because of the requirement for specific annealing when forming a RNA-RNA duplex as argued by the Examiner in the enablement rejection of previous office action dated 12/02/2002. Furthermore, the limitations now recited in the claims with respect to hybridization conditions and 80% sequence identity (response page 15-16) are not enabling because the sequences that would fall within this range and proposed for use in the non-exemplified methods of the invention are not described and would require undue experimentation to eliminate non-functional embodiments. It is noted that Claim 84 is not limited to any particular means of "regulating" gene expression, and Claims 85 and 87 do not recite any degree of sequence identity. In addition, with respect to the allegedly inconsistent rejections under 35 U.S.C. 112 and 35 U.S.C. 103 (response page 14), the Examiner maintains that the test for adequacy of a prior art disclosure to anticipate or render claims obvious is not the same test as that for adequacy of a patent application disclosure to support claims under 35 U.S.C. 112, as taught in *In re Hafner*, 161 USPQ 783, (CCPA 1969). Furthermore, the art rejection has not been maintained, as stated below.

Claims 1-7, 12-18, 22-28, 32-38, 42-47 remain and new Claims 84-91 are rejected.

Claims 1-8, 11-19, 22-39, 42-47, and 84-91 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide encoding a flavanone-7-O-glucoside-2"-O-rhamnosyl-transferase from pomelo or which has at least 80% similarity thereto, or methods of use.

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Claims 8, 11, 19, 29 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.  
August 15, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

